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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/748,764	12/30/2003	Madhav S. Thakur	ORT-0957-USA-DIV	8725

27777 7590 11/28/2005
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EXAMINER

VENKAT, JYOTHSNA A

ART UNIT PAPER NUMBER

1615

DATE MAILED: 11/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/748,764	Applicant(s) THAKUR ET AL.	
	Examiner JYOTHSNA A. VENKAT Ph. D	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-23 and 26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-23 and 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/13/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of Remarks and IDS filed on 9/6/05 and 6/13/05. Claims 15-23 and 26 are pending in the application and the status of the application is as follows:

The following new ground of rejection is necessitated by the amendment.

Claim Rejections - 35 USC § 103

1. Claims 15-23 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of PDR (page 2058 of the 52d edition) and U. S. Patents 5,260,072('072) and 5,133,974 ('974) and 5,048,278 ('278).

The instant application is claiming method of treating convulsions administering pharmaceutical compositions comprising:

1. Core particles containing the active ingredient Topiramate and binder (species is povidone) and diluent which are sugar spheres
2. Taste masking coating, which has disintegrant (povidone) and taste masking agent (cellulose acetate) and the coated particles are sprinkled onto soft food for swallowed.

The PDR teaches topiramate as a drug having bitter taste and the drug useful as an epileptic drug. The PDR does not teach the composition claimed core particles and taste masking coating. However patent '072 teaches rotogranulation and taste masking coatings for the preparation of chewable pharmaceutical tablets using drug, which has the bitter taste along with binder povidone and taste masking coating, which is cellulose acetate. See the abstract, and see col.3, lines 55-65 and see col.4, lines 40-55. The patent teaches lactose as the carrier and teaches that other saccharides can be used. The patent at paragraph bridging cols 4-5 and col.5, lines 3-52 teach coating with cellulose acetate and povidone. Patent '974 is relied for the teaching of sugar

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spheres. Patent '974 teaches pharmaceutical preparations using core having the drug, sugar spheres, binder and coated with film forming agent. The particle size of the core particles is same to that of coated particles. See claim 1 and see col.col.4, lines 1-25, and col.5. Patent '278 teaches taste-masked pharmaceutical compositions. See the abstract, see col.1, lines 14-17, col.2, lines 51-55 and see col.2, lines 61-66, where the patent not only teaches chewable taste-masked formulations, but also teaches that the formulations can be in "sprinkle" form that can provide immediate release of active agent in the stomach. See col.6, lines 43-45, col.9, lines 45-55, and col.10, lines 9-16 where the patent teaches sprinkle form for bitter tasting drugs. See also claim 15 where different bitter tasting drugs are claimed.

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare compositions using the process of '072 and substitute topiramate taught by PDR having bitter taste for fomatidine and use sugar spheres in the core particles taught by '974 and use the formulation of '072 in sprinkle form taught by patent '278 for bitter tasting drugs expecting beneficial effect. One of ordinary skill in the art would be motivated to prepare compositions of '072 and substitute topiramate for fomatidine with the reasonable expectation of success that the pharmaceutical composition exhibit better balance between taste masking, dissolution and rate of bioavailability and adding sugar spheres in the core aids in the diffusion/release of the drug from the formulation and sprinkle the formulation on food provide immediate release of Topiramate in the stomach, delayed release of Topiramate in the upper intestinal tract. Topiramate is an epileptic drug and providing the drug in sprinkle form on food or cereal is better than chewable form for children. It is a prima facie of obviousness.

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2. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

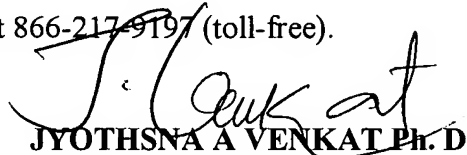
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JYOTHSNA A. VENKAT Ph. D whose telephone number is 571-272-0607. The examiner can normally be reached on Monday-Friday, 10:30-7:30: 1st Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, THURMAN K. PAGE can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


JYOTHSNA A VENKAT Ph. D
Primary Examiner
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1.